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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,776	01/15/2004	David K. Boehm	06882.0096-00	5457

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EXAMINER	
DORNBUSCH, DIANNE	
ART UNIT	PAPER NUMBER
3773	
MAIL DATE	DELIVERY MODE
01/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/757,776	BOEHM ET AL.	
	Examiner	Art Unit	
	DIANNE DORNBUSCH	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5, 7-17, 19-37* is/are pending in the application.

4a) Of the above claim(s) *24-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-17, 19-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofert et al. (4,203,446).

Hofert discloses the following claim limitations:

Claim 10: A rearward body assembly of a lancing device that can propel a lancet (12) into a lancing surface, the rearward body assembly comprising: a lancet holder (16) comprising one or more retaining features (14) and one or more spring surfaces (the outer area and the top surfaces of the lancet holder are spring surfaces since the surface is in contact with the springs); an interior tube (34) comprising an open end (proximal end as seen in the Figure) and a slotted end (distal end where it is stepped as seen in the Figure) through which the one or more retaining features (14) extend (see the Figure), the interior tube (34) being adapted to slidably engage the lancet holder (16) (the lancet holder is placed inside the inner tube as seen in the Figure); a finger cover (18) (note that the finger cover according to applicant's drawings is a collar that goes over the interior tube as best seen in Fig. 3 of the current application) arranged along a periphery of the interior tube (see Figure); an internal compression spring (36) comprising a first end and a second end (see Figure), the first end of the internal

compression spring (36) being adapted to act on the slotted end of the interior tube (34) (the proximal end of the spring is in contact with the slotted area as seen in the Figure) and the second end of the internal compression spring (36) being adapted to act on the one or more spring surfaces of the lancet holder (16) (the distal end is in contact with the lancet holder so when a force is applied on the spring it will act on the spring surfaces); a retainer (14) comprising a slotted surface (it has a slot in the center where the lancet is slid through) through which the one or more retaining features extend (the retaining features of 14 are the walls external and internal which compress the lancet in place); a rearward body (combination of 24 and 22), the rearward body engaging the retainer (14) (when the rearward body is displaced in the forward direction it will engage with the retainer); and an external compression spring (20) comprising a first end and a second end (see the Figure), the first end comprising a reduced coil diameter that engages the one or more retaining features (14) of the lancet holder (16) as seen in the Figure, the first end of the external compression spring being adapted to act on the lancet holder (the spring is holding the lancet holder which will act on it to cause the deployment of the lancet) and the second end of the external compression spring being adapted to act on the slotted surface of the retainer (the spring is compressing on the retainer therefore it is acting on the slotted surface); and wherein longitudinal movement of the rearward body away from the interior tube compresses the interior compression spring (Col. 3 Lines 5-10).

Claim 11: That the lancet holder (16) further comprises a trigger extension (22), the trigger extension being adapted to engage both a trigger and the interior tube to load

the lancing device and to oppose the force of the compression spring until the trigger is actuated. It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Claim 12: That the retainer (14) further comprises one or more retainer alignment features (the step portion and the end of the lancet holder (16) serve as alignment features that maintain the retainer centered), and the rearward body (combination of 24 and 22) further comprises one or more rearward body alignment features (the piece 24 serves as an alignment feature which has to fit on the center of the lancet holder (16) which has the retainer (14)) that can engage the one or more retainer alignment features. The rearward body engages to the step portions of the retainer which maintains the rearward body centered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-3, 5, 7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morita (5,730,753) in view of Abulhaj et al. (6,852,119).

Claim 1: Morita discloses an adjustable nozzle assembly (1) through which a lancet can be propelled by a lancing device into a lancing surface, the adjustable nozzle assembly (1) comprising: an interior nozzle (3 specifically the top part 11) comprising a ramped

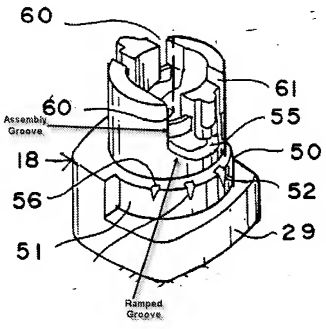
groove (47) and a lancet wall (13); a collar (5) comprising a collar pin (53) that engages the ramped groove (47) and slides relative to the ramped groove (Col. 12 Lines 65-68 and Col. 13 Lines 9-14), the collar (5) being adapted to rotate relative to the interior nozzle (3,11) (Col. 12 Lines 12-15); and an exterior nozzle (7) comprising a contact surface (35) that extends beyond the lancet wall (13) of the interior nozzle (3,11) to contact the lancing surface (Fig. 1), the exterior nozzle (7) engaging the collar (5) (Col. 13 Lines 50-53) and being adapted to rotate relative to the interior nozzle (3,11) (Col. 13 Lines 58-60); and wherein the ramped groove (47) is sloped (Fig. 1) such that as the exterior nozzle (7) rotates relative to the interior nozzle (3, 11), the distance that the contact surface (35) extends beyond the lancet wall (13) changes by an amount that corresponds to the slope of the ramped groove (Col. 14 Lines 1-9).

Furthermore, Morita discloses an assembly groove (the distal end of the groove 47 which is straight in one portion), and that the collar pin (53) is configured to slide through the assembly groove to the ramped groove. The collar pin first slides to the distal end of the groove which is the assembly groove and then slides down to where the groove is ramped which is the ramped groove as seen in Fig. 1-2.

Morita discloses all the claimed limitations discussed above however, Morita does not disclose that the ramped groove is extending in a second direction deviating from the first direction in which the assembly groove extends.

Abulhaj discloses a lancet with an adjustable depth mechanism in which a cap (18) is adjustable by a pin/groove mechanism (Fig. 15-16 where the pin (31) enters the groove seen in the figure below) where the groove has an assembly groove (see figure

below) extending in a first direction (it extends longitudinally from the proximal end towards the distal end) and a ramped groove (see figure below) extending in a second direction (it extends diagonally as seen in the figure below) deviating from the first direction (see figure below).



The substitution of one known element (the ramped and assembly groove of the threaded mechanism of Morita) for another (the ramped and assembly groove of the pin/groove mechanism of Abulhaj) would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution of two well known connection mechanisms (pin/groove and threaded) which are used as depth mechanism such as the one shown in Abulhaj would have yielded predictable results of an adjustable depth mechanism.

Additionally, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Morita with the pin/groove mechanism that contains an assembly groove extending in a direction which is deviated form the direction of the ramped groove, in order to have an entry point for the pin which would allow the pin to slid straight through until the ramped groove is reached.

Claim 2: Morita discloses that the collar (5) further comprises a plurality of adjustment notches (51, 57) and wherein the interior nozzle (3, 11) further comprises a cantilevered detent (39, 41) that can engage the cantilevered detent (Fig. 2).

Morita discloses the claimed invention except for the location of the notches and the detents, where the notches are in the collar and not in the interior nozzle and the detents are in the interior nozzle not on the collar. It would have been obvious to one having ordinary skill in the art at the time the invention was made have the notches on the interior nozzle and the recess on the collar, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Claim 3: Morita discloses that the collar (5) further comprises a sloped collar ramp (the collar ramp at the portion that contains the pin 53), the sloped collar ramp comprising a detent (the ramp of the detents between pin 53); and the interior nozzle (3,11) further comprises a sloped interior nozzle ramp (17), the sloped interior nozzle ramp (17) comprising a plurality of adjustment notches (the notches sticking out between the groove 47 where each time the circumference is completed a new notch is found) that can engage the detent (Fig. 2); and wherein the slope of the collar ramp, the slope of

the interior nozzle ramp, and the slope of the ramped groove are approximately equal (Fig. 2 and Col. 13 Lines 5-8).

Claim 5: Morita discloses that the detent (the ramp of the detents between pin 53) forms a slotted portion (Fig. 3 where the detents are in the central portion of the collar) of the collar ramp (the collar ramp at the portion that contains the pin 53).

Claim 7: Morita discloses that the collar (5) further comprises one or more collar alignment features (29, 25), and the exterior nozzle (7) further comprises one or more exterior nozzle alignment features (65, 55) that can engage the one or more collar alignment features (Col. 13 Lines 45-49 and Col. 14 Lines 28-30).

Claim 9: Morita discloses that the ramped groove (47) comprises an over-rotation groove. The ramped groove (47) has ends which are thinner which would not allow the collar (5) to rotate more than that point. Furthermore, the interior nozzle has a stopper (43) which will stop the device one component (25) of the collar (5) hit it. This is a prevention to over-rotation in addition to the end of the groove (47).

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morita (5,730,753) in view of Abulhaj et al. (6,852,119) and further in view of Bajaj et al. (6,056,765).

Morita in view of Abulhaj discloses all the claimed limitations discussed above however, Morita in view of Abulhaj does not disclose that the detent forms a cantilevered portion of the collar ramp.

Bajaj discloses that the detent (136 shown in Fig. 1 on component 104) forms a cantilevered portion of the collar ramp (Fig. 1).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Morita in view of Abulhaj with a detent that forms a cantilever in view of the teachings of Bajaj, in order to provide a flexible portion of the collar that can store the energy and serve as a cushion when the device is place on the lancet surface and ejected.

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morita (5,730,753) in view of Abulhaj et al. (6,852,119) and further in view of Duchon et al. (5,964,718).

Morita in view of Abulhaj discloses all the claimed limitations discussed above however, Morita in view of Abulhaj does not disclose that the contact surface is concave.

Duchon discloses that the contact surface (48) is concave (Col. 5 Lines 28-30 and Fig. 13)

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Morita in view of Abulhaj with a concave contact surface in view of the teachings of Duchon, in order to have a contact surface that adjusts to the lancing surface with minimal impact on the lancing surface.

7. Claims 13-15, 17, 19, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofert et al. (4,203,446) in view of Morita (5,730,753) and further in view of Abulhaj et al. (6,852,119).

Claims 13, 15, 17, 19, and 21-23:

Hofert teaches all the claimed limitations discussed above (see rejections of claims 10-12 which reads on the rearward assembly of claims 13, 22, and 23) however, Hofert does not disclose an adjustable nozzle assembly.

Morita discloses all the features of the adjustable nozzle claimed in claims 15, 17, 19, and 21 (refer to rejections of claims 1, 3, 5, 7, and 9).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Hofert with an adjustable nozzle in view of the teachings of Morita, in order to adjust the puncturing depth of the lancet on the tissue which will adapt to different skin thickness or change the amount of blood that needs to be collected.

Hofert in view of Morita discloses all the claimed limitations discussed above however, Hofert in view of Morita does not disclose that the ramped groove is extending in a second direction deviating from the first direction in which the assembly groove extends.

Abulhaj discloses a lancet with an adjustable depth mechanism in which a cap (18) is adjustable by a pin/groove mechanism (Fig. 15-16 where the pin (31) enters the groove seen in the figure above in the rejection of claim 1) where the groove has an assembly groove (see figure above in the rejection of claim 1) extending in a first direction (it extends longitudinally from the proximal end towards the distal end) and a ramped groove (see figure above in the rejection of claim 1) extending in a second direction (it extends diagonally as seen in the figure above in the rejection of claim 1) deviating from the first direction (see figure above in the rejection of claim 1).

The substitution of one known element (the ramped and assembly groove of the threaded mechanism of Morita) for another (the ramped and assembly groove of the pin/groove mechanism of Abulhaj) would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution of two well known connection mechanisms (pin/groove and threaded) which are used as depth mechanism such as the one shown in Abulhaj would have yielded predictable results of an adjustable depth mechanism.

Additionally, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Hofert in view of Morita with the pin/groove mechanism that contains an assembly groove extending in a direction which is deviated form the direction of the ramped groove, in order to have an entry point for the pin which would allow the pin to slid straight through until the ramped groove is reached.

Claim 14: Morita discloses that the collar (5) further comprises a plurality of adjustment notches (51, 57) and wherein the interior nozzle (3, 11) further comprises a cantilevered detent (39, 41) that can engage the cantilevered detent (Fig. 2).

Therefore Hofert in view of Morita and further in view of Abulhaj discloses the claimed invention except for the location of the notches and the detents, where the notches are in the collar and not in the interior nozzle and the detents are in the interior nozzle not on the collar. It would have been obvious to one having ordinary skill in the art at the time the invention was made have the notches on the interior nozzle and the

recess on the collar, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hofert et al. (4,203,446) in view of Morita (5,730,753) and Abulhaj et al. (6,852,119) and further in view of Bajaj et al. (6,056,765).

Hofert in view of Morita and Abulhaj discloses all the claimed limitations discussed above however, Hofert in view of Morita and Abulhaj does not disclose that the detent forms a cantilevered portion of the collar ramp.

Bajaj discloses that the detent (136 shown in Fig. 1 on component 104) forms a cantilevered portion of the collar ramp (Fig. 1).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Hofert in view of Morita and Abulhaj with a detent that forms a cantilever in view of the teachings of Bajaj, in order to provide a flexible portion of the collar that can store the energy and serve as a cushion when the device is place on the lancet surface and ejected.

9. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hofert et al. (4,203,446) in view of Morita (5,730,753) and Abulhaj et al. (6,852,119) and further in view of Duchon et al. (5,964,718).

Hofert in view of Morita and Abulhaj discloses all the claimed limitations discussed above however, Hofert in view of Morita and Abulhaj does not disclose that the contact surface is concave.

Duchon discloses that the contact surface (48) is concave (Col. 5 Lines 28-30 and Fig. 13)

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Hofert in view of Morita and Abulhaj with a concave contact surface in view of the teachings of Duchon, in order to have a contact surface that adjusts to the lancing surface with minimal impact on the lancing surface.

Response to Arguments

10. Applicant's arguments with respect to claims 1-9, 13-17 and 19-23 have been considered but are moot in view of the new ground(s) of rejection.

11. Applicant's arguments filed November 11, 2008 regarding the rejection of claims 10-12 have been fully considered but they are not persuasive.

Applicant argues that Hofert does not disclose a finger cover. The examiner respectfully disagrees, since according to the applicant's drawings, the finger cover is a collar that goes over and covers a portion of the interior tube as best seen in Fig. 3 of the current application. With this in mind, the device of Hofert has a collar/cover (18) around the interior tube (34) as seen in the Figure.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773